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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,414	09/18/2001	Nancy L. Parenteau	56001/02021	1042

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ORGANOGENESIS  
150 DAN ROAD  
CANTON, MA 02021

11/17/2008

EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

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11/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/955,414	<b>Applicant(s)</b> PARENTEAU ET AL.	
	<b>Examiner</b> Paul B. Prebilic	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 7-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 7-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 7-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The range of “inserting at least a first cultured connective tissue construct” lacks original support. It is noted that 37 CFR 1.114 does not allow the introduction of new matter as is done in the continuation-in-part practice.

In addition, the combination of a step of inserting at least a cultured connective tissue into the opening where at least a second construct is used to close the opening lacks original support as well.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoval (WO 99/04720) in view of Murphy et al (WO 00/29553) and Lambrecht et al (US 7,220,281). Stoval discloses a method of forming an opening in an annular fibrosis

(see page 10, line 1 to page 11, line 12 and Figure 2), removing at least a portion of the nucleus pulposus (see *supra*), inserting a first cultured construct (injection (80) of Stovall), and grafting a cultured connective tissue construct (the second construct as claimed) to close the opening (see page 2, lines 10-18, page 3, lines 7-14, and page 4, lines 10-15). The layer of extracellular matrix as claimed is met by the layer of extracellular matrix material that is inherently present around the cultured cells of Stoval.

However, Stoval fails to clearly disclose using a bioremodelable construct in the method as claimed. Murphy teaches that it was known to make bioremodelable graft constructs without exogenous matrix components or synthetic members in the repair a variety of tissues; see pages 1-19 and claim 19 thereof and see the present specification and the paragraph bridging pages 5 and 6. Lambrecht teaches that it was known to both insert a first repair material into the opening and to graft a second material to close the opening as claimed; see Figure 26, column 19, line 18 et seq. and the paragraph bridging columns 26 and 27.

Particularly, Murphy teaches the use of bioremodelable constructs as replacements or improvements over those constructs of the art that relied upon mesh supports; see page 10, lines 21-29. Murphy also discloses that any tissue type can be used to replace the corresponding tissue; see page 19, lines 7-17. In this way, Murphy provides a nexus from prior art constructs of Stoval to the use of the constructs disclosed therein that do not have exogenous support materials or synthetic materials.

Lambrech teaches that it was known to repair both the opening the defect of the same disc during so as to render the claimed method *prima facie* obvious. Because of the new matter added to the claims, the Examiner asserts that the present claims have an effective filing date of October 25, 2007, which is the day that the amendment to the claims was filed.

Therefore, it is the Examiner's position that it would have been obvious to use the bioremodelable construct of Murphy as the graft implant material of Stoval for the same reasons that Murphy teaches using the same. And it would have been obvious to repair both the defect and the opening as taught by Lambrecht for the reasons that Lambrecht teaches doing the same.

With regard to the paragraph bridging pages 5 and 6 of the present specification, it is noted that MPEP 715 states:

"Where applicant has clearly admitted on the record that subject matter relied on in the reference is prior art. In this case, that subject matter may be used as a basis for rejecting his or her claims and may not be overcome by an affidavit or declaration under 37 CFR 1.131. In re Hellsund, 474 F.2d 1307, 177 USPQ 170 (CCPA 1973); In re Garfinkel, 437 F.2d 1000, 168 USPQ 659 (CCPA 1971); In re Blout, 333 F.2d 928, 142 USPQ 173 (CCPA 1964); In re Lopresti, 333 F.2d 932, 142 USPQ 177 (CCPA 1964)"

Regarding claim 3, since extracellular matrix is made of collagen, the same is present in the constructs of Stoval or Murphy.

### ***Response to Arguments***

Applicants' arguments filed August 26, 2008 have been fully considered but were considered unpersuasive.

The Applicant argues that there is original support for “inserting at least a first cultured connective tissue construct” is on page 5 of the specification; see page 6 of the response. However, the Examiner notes that the language “one or more” not “at least one” is utilized thereon. The language “at least one” can be construed differently than “one or more” in that “one or more” suggests “or more” is an optional additional component because the emphasis is on “one.” The Examiner suggests changing “at least one” to ---one or more--- in order to overcome this rejection. This change should not cause the Applicant difficulty if the Applicant truly believes the language “one or more” is identical to “at least one.”

The Applicant argues that Stovall does not teach inserting the first construct into the opening and grafting the second construct to close the opening. However, the Examiner asserts that both the first and second constructs of Stovall are inserted and grafted in a manner that is clearly obvious over Stovall. The fact that Stovall closes the opening and injects the first construct does not render the claimed invention patentable because it is a mere changing the sequence of steps in an obvious manner; see MPEP 2144.04 IV C that is incorporated herein by reference.

The Applicant also argues that there is no step of grafting and suturing the second construct to close the opening. However, this step is clearly set forth in Stovall in the paragraph bridging pages 10 and 11.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Preblich whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 3774